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**510(k) Summary**

**CardioBeeper® CB-12L**

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**1. Sponsor**

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**2. Device Name**

Classification Name: Telephone Electrocardiograph Transmitter

Proprietary Name: CardioBeeper® CB-12L

**3. Intended Use**

The CardioBeeper® CB-12L is intended to condition an electrocardiograph signal so that it can be transmitted via a telephone line to a remote location. The CB-12L is designed to be used by a patient to transmit a rhythm strip or a 12 lead ECG signal in real time to a physician's office, hospital or other medical receiving center. Note that due to the discrete options for selecting the precordial electrode positions, the CB-12L transmission may only approximate a standard 12 lead ECG for some patients.

**4. Device Description**

The CardioBeeper® CB-12L is a compact, hand-held, battery-powered, single channel transtelephonic ECG transmitter that is capable of transmitting a 24 second

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rhythm strip or a 45 second 12 lead ECG. The CB-12L consists of a transmitter/electronics module (TEM), two limb electrodes (RA and LL) attached to the TEM via separate cables, and a chest belt containing the third limb electrode (LA) and thirteen silver silver-chloride electrodes. Prior to a patient using the CB-12L, the patient's physician must select the six most appropriate chest belt electrodes to function as the precordial V1-V6 electrodes according to the patient's chest size. Technical specifications for the CB-12L are as follows:

Low End Frequency Response	0.05 Hz
High End Frequency Response	150 Hz min.
Common Mode Rejection Ratio	80 dB min.
System Noise	<40 $\mu$ V r.t.i.
Input Dynamic Range	$\pm 2.3$ mV
Frequency Modulation	FM
Carrier Frequency	1700 $\pm 20$ Hz
Deviation Sensitivity	127.5 Hz/mV $\pm 5\%$
Battery	9V alkaline

#### 5. Basis For Substantial Equivalence

The CardioBeeper® CB-12L is substantially equivalent to other telephone electrocardiograph transmitters that have received 510(k) clearance for use by the patient in transmitting ECG information from a remote location to a physician's office, hospital, or other medical receiving center. Specifically, the rhythm strip operation of the CB-12L is substantially equivalent to the single-lead operation of the CardioBeeper® CB300 Memory Monitor (K813101), and the 12 lead operation of the CB-12L is substantially equivalent to the multiple-lead operation of the Card Guard 9000 (K924486) and the Aerotel Heartview (K950004).

A clinical study was conducted with a study population of 97 patients in order to: (1) compare the diagnostic quality of 12 lead ECGs recorded using the CB-12L to those recorded using a standard 12 lead ECG system; and (2) compare the diagnostic quality of ECGs transmitted using the CB-12L with and without physician supervision. The results of the study showed that the ECGs transmitted using the CB-12L were comparable in diagnostic content to those recorded using a standard 12 lead machine. In addition, the results confirmed that the patients were capable of applying the electrodes and transmitting a quality 12 lead ECG tracing without direct medical supervision following appropriate training in the use of the CB-12L.